

REMARKS

Applicant submits this amendment in response to an Office Action mailed by the USPTO on September 21, 2004 (the "Office Action").

By this amendment applicant has amended claims 15 and 32. Upon entry of this amendment, claims 15, 19-33 and 36-37 shall be in the present application.

In the Office Action, the Examiner has rejected claims 15, 19-33 and 36-37 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,955,871 of Thomas or Taylor (applicant is unable to locate a reference to Taylor in the present application.) in view of U.S. Patent Nos. 5,417,662 and 5,873,856 of Hjertman, et al. (Hjertman I and Hjertman II), and U.S. Patent No. 4,373,526 of Kling. Applicant respectfully traverses that rejection.

The Examiner notes that the Thomas discloses "a drug container having a reservoir adapted to contain a selected substance and an outlet port that allows the substance to exit the reservoir during an injection, wherein said drug container comprises a syringe having a generally flat body portion that at least partially surrounds the reservoir, the body portion and the reservoir being made from two sheets of thermoplastic material such that side walls of the reservoir are selectively deflectable toward each other to expel a substance from the reservoir during an injection., and a needle in fluid communication with the outlet port, the needle having a forward end that is adapted to penetrate the skin of an animal. The Examiner notes that Thomas does not disclose a limiter that surrounds the needle. Applicant does not disagree with the Examiner on those points.

To fill the void in the disclosure of Thomas, the Examiner looks to Hjertman, et al. and Kling. Hjertman I discloses a limited depth penetration needle housing that facilitates "injection,

especially subcutaneous injection.” See, e.g., column 1, lines 1-2 of U.S. Patent No. 5,873,856. Thus, insofar as Hjertman I teaches a device for limiting an injection depth of a needle, that teaching is limited to subcutaneous injections.

Hjertman II also discloses a device for limiting the penetration of an injection needle. The device includes a sleeve (1) that is displaceable rearwards against the force of a spring during an injection. After the injection is complete, the spring causes the sleeve (1) to return to a starting position. See, e.g., FIGS. 1 and 2. Similarly, Kling discloses a device having a movable sleeve (1) that limits the injection depth of a needle to the intramuscular or subcutaneous areas of the skin.

Thus, applicant respectfully submits that the shortcomings of Thomas are not overcome by the teachings or suggestions of Hjertman et al. or Kling. The Examiner’s proposed combination of Thomas and Hjertman et al. and Kling teaches an injection device having a movable limiter (Hjertman I and II and Kling) that controls the depth of injection of the needle to the subcutaneous (Hjertman I and Kling) or intramuscular (Kling) areas of the skin. Applicant respectfully submits that such teachings do not render the claims of the present application obvious. Applicant’s invention is directed to an intradermal delivery device for making intradermal injections that comprises, *inter alia*, a non-movable limiter that limits penetration of the needle to the dermis layer of the skin. Applicant respectfully submits that none of the prior art references relied upon by the Examiner in the Office Action, nor any other prior art references of record in the present application, teach or suggest such a device.

In view of the forgoing remarks, applicant respectfully submits that the Examiner’s rejection of claims 15, 19-33 and 36-37 as being unpatentable over Thomas [or Taylor] in view

Application No.: 09/825,017
Amendment Dated March 24, 2005
Reply to Office Action of September 21, 2004
Page 8

of Hjertman, et al. and Kling is no longer tenable, and respectfully requests withdrawal of that rejection.

Applicant respectfully submits that this amendment is fully responsive to the Office Action, and that claims 15, 19-33 and 36-37 are patentable over the prior art of record in the present application, and are thus in condition for allowance. Applicant thus respectfully requests early and favorable reconsideration of the present application.

With the exception of the fees required in connection with applicant's Petition to Revive and Petition for Extension of Time, both filed concurrently herewith, applicant believes there are no other fees due in connection with this amendment. However, if any such fees are due, applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this amendment, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

Dated: March 24, 2005

By: David Fortunato
David M. Fortunato
Attorney for Applicant(s)
Reg. No. 42,548
(201) 847-6940